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Patents, Trademarks,
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April 25, 2000

VIA EXPRESS MAIL LABEL NO. EL634190716US
BOX PATENT APPLICATION

Honorable Commissioner of Patents
and Trademarks
Washington, D.C. 20231

RE: U.S. Patent Application
Inventor: David W. Cunningham
METHOD AND SYSTEM FOR DISPENSING, TRACKING AND
MANAGING PHARMACEUTICAL PRODUCTS

Dear Sir:

Enclosed please find the above-identified U.S. Patent Application, which includes the following:

1. Specification and Claims
2. Formal Drawings (3 sets of 14 sheets)
3. Declaration and Power of Attorney for Patent Application
4. Declaration Claiming Small Entity Status
5. Fee Transmittal Sheet
6. **Express Mail Certification - Label No. EL634190716US**
6. Check No. 1454
7. Postcard

Also enclosed please find our check in the amount of **\$384.00** to cover the Government Filing Fee and recordation of the Assignment. If fees are not sufficient, please deduct from our Deposit Account No. 18-1167.

Respectfully submitted,

COATS & BENNETT, P.L.L.C.

By:

Larry L. Coats
Larry L. Coats

Registration No. 25,620

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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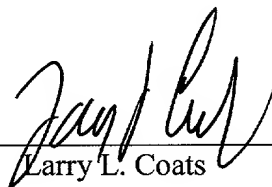
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Date of Deposit April 25, 2000

I hereby certify that the enclosed specification and claims for **METHOD AND SYSTEM FOR DISPENSING, TRACKING AND MANAGING PHARMACEUTICAL PRODUCTS**, drawings, Utility Patent Application Transmittal, Fee Transmittal and duplicate, Declaration, Power Of Attorney, and our Check No. 1454 in the amount of \$384.00, are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to Box Patent Application, Assistant Commissioner for Patents, Washington, D.C. 20231.

Mailed By: _____


Larry L. Coats

DECLARATION CLAIMING SMALL ENTITY STATUS

I declare that I am an independent inventor and have (1) not assigned, granted, conveyed nor licensed this invention, and (2) am under no obligation under contract, law nor otherwise, to assign, grant, convey or license any rights in this invention including (i) the right to make, use or sell the invention, and (ii) the right to exclude others from making, using or selling the invention to any person who could not likewise be classified as an independent inventor if that person had made the invention, or to any concern which would not qualify as a small business concern or a non-profit organization under §1.9 of the Patent Office Rules of Practice.

I hereby declare additionally that all statements made herein of my own knowledge is true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 4/25/00


David W. Cunningham

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Date Mailed: April 25, 2000

UNITED STATES PATENT APPLICATION FOR GRANT OF LETTERS PATENT

**DAVID W. CUNNINGHAM
INVENTOR**

METHOD AND SYSTEM FOR DISPENSING, TRACKING AND MANAGING PHARMACEUTICAL PRODUCTS

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METHOD AND SYSTEM FOR DISPENSING, TRACKING AND MANAGING PHARMACEUTICAL PRODUCTS

RELATED APPLICATIONS

The present application is a continuation-in-part of U.S. Patent Application Serial No. 09/137,095, filed 20 August 1998, now U.S. Patent 6,055,507, which is a divisional application of U.S. Patent Application Serial No. 08/556,466, filed 13 November 1995, now U.S. Patent No. 5,832,449, the disclosures of both of which are hereby expressly incorporated by reference.

FIELD OF THE INVENTION

The present invention relates generally to the distribution of pharmaceutical products and more particularly to an improved method of dispensing, tracking, and managing pharmaceutical products by communicatively linking prescribers and pharmacies to a central computing station.

BACKGROUND OF THE INVENTION

In the pharmaceutical industry, the primary method for product promotion of ethical products is the use of outside sales representatives. Company sales representatives target specific physicians and detail the features and benefits of particular pharmaceutical products. Pharmaceutical manufacturers have documented that the most effective method of product promotion involves providing pharmaceutical product samples to prescribers of the products who then pass along the product samples to patients. Physicians therefore receive numerous quantities of pharmaceutical product samples for purposes of conducting patient trials. These trials enable physicians to determine the effectiveness of certain drugs in certain patients for certain diseases, as well as to determine patients' tolerance of the drugs and their compliance with drug administration directions.

A responsibility of the Food & Drug Administration (FDA) is the regulation of pharmaceutical product samples. The PDMA (Pharmaceutical Drug Manufacturing Act) Act of 1987 requires pharmaceutical manufacturers to track and account for product samples distributed by sales representatives to prescribing physicians. Pharmaceutical manufacturers are required to account for all sample product inventories, as well as the time, location, and specific physicians who receive promotional samples. Pharmaceutical sales representatives are required to record receipts of product samples, adjustments to sample inventories, and distribution of product samples, and to report any loss or theft of product samples. Additionally, PDMA warehousing requirements dictate inventory storage methods and locations both within pharmaceutical companies themselves and for outside pharmaceutical sales representatives.

However, it is often the case that accountability for pharmaceutical product samples ends when the samples reach the physicians. Most physicians do little to account for their inventories of product samples. Rather, physicians tend to distribute pharmaceutical product samples to patients much more informally than retail pharmacies, keeping few if any records and often not even counting the precise number of product samples given to patients.

The PDMA's accountability requirements increase pharmaceutical manufacturers' expenses for promoting and distributing product samples as well as the complexity of administering sampling programs. As competition within the pharmaceutical industry increases, costs associated with product samples place an increasingly greater burden on the pharmaceutical manufacturers. Pharmaceutical manufacturers are therefore attempting to reduce expenses and maintain acceptable profits while incorporating the PDMA's new requirements into established promotional practices.

Although product samples are an extremely effective promotional tool, the manufacturing of drug product samples in addition to normally packaged drug products has proven to be increasingly costly. Pharmaceutical product samples are typically elaborately and expensively packaged and are extremely bulky compared to normally packaged drug products. Pharmaceutical manufacturers must utilize separate product sample packaging lines to specially package drug product samples. Distribution of product samples requires delivery via separate carriers and distribution routes. In addition, drug product samples are typically warehoused separately from normally packaged drug products.

Because the current climate in the pharmaceutical industry prohibits the unrestrained shifting of costs to final consumers, pharmaceutical manufacturers have taken several new approaches to reducing costs associated with promoting product samples. Nevertheless, pharmaceutical manufacturers are attempting to maintain the marketing advantages of using sales representatives to distribute product samples.

One cost-reducing approach that pharmaceutical manufacturers have attempted is the distribution of sample vouchers to prescribing physicians, retail pharmacies, and pharmaceutical sales representatives. With this approach, instead of giving drug product samples directly to patients, physicians give the patients vouchers for the drug product samples. The vouchers may then be redeemed at retail pharmacies for the actual drugs. Alternately, the patients may receive cash or credit rebates at the pharmacies.

Another cost-reducing approach that pharmaceutical manufacturers have attempted is the distribution of product samples via mail order. With this approach, pharmaceutical sales representatives provide prescribing physicians with request authorization forms. Physicians then

use the forms to authorize deliveries of product samples directly to physician office from third-party pharmaceutical supply warehouses.

The above new approaches to distributing pharmaceutical product samples have not met with substantial and universal acceptance. All of these approaches lack an effective, efficient and practical system for distributing the trial or sample products to patients and at the same time recording pertinent data, which is easily accessible, relating to prescribing and dispensing the pharmaceutical trial products.

Additionally, there are strict rules associated with the dispensing of pharmaceuticals outside of the sample context. In particular, prescriptions are closely monitored by the appropriate government agencies. To help combat prescription fraud, new systems must be developed that allow prescription drugs to be tracked such that appropriate reporting may be performed about the dispensation of prescription drugs outside the sample context. Thus, there remains a need for alternative prescription routines that address these needs.

SUMMARY AND OBJECTS OF THE INVENTION

The present invention entails a system and method for managing and tracking the distribution of pharmaceutical trial or sample products by utilizing medical prescribers and pharmacies. Instead of the medical prescriber directly delivering pharmaceutical trial products to patients, the present system and method contemplates the prescriber prescribing a pharmaceutical trial product to a patient and the filling of that prescription by a participating pharmacy. This method and program is managed through a central computing station that is communicatively linked to terminals located at participating prescriber and pharmacy sites. This system, as will be discussed in greater detail below, manages, tracks, and records selected transactions involving the participating prescribers, pharmacies and patients.

To identify various pharmaceutical trial products, the system utilizes a medium, such as a magnetic card, which is encoded with specific information that particularly identifies a certain pharmaceutical trial product. Encoded media is then distributed to participating medical doctors or prescribers. Once the encoded product trial media is received by the prescribers, the prescribers then activate the selected product trial media. Activation is accomplished, in part at least, by utilizing a prescriber terminal to communicatively link the selected product trial media with the central computing station or host. Once the product trial media has been activated, the prescriber then transfers the activated product trial media to patients. The patients then present the activated product trial media to participating pharmacies. Prior to filling the prescriptive pharmaceutical trial product identified by the media, the pharmacy engages in a procedure designed to validate the patient-presented pharmaceutical trial media. To validate the presented product trial media, the pharmacy communicatively links the presented media to the central computing station via the pharmacy terminal. After making selected verifications, the central computing station validates the presented product trial media. Validation results in the pharmacy dispensing the pharmaceutical trial product identified by the presented media.

Prior to activation and validation, the system and method of the present invention requires that the participating pharmacies and prescribers establish "authorization", that is that they are in fact authorized participants in the pharmaceutical trial product distribution program.

After validation and dispensing, a database associated with the central computing station will have recorded the activation and validation transactions and other data related thereto. Based on the recorded data, audit and accounting procedures can follow. Particularly, dispensed pharmaceutical trial products can now be replaced at the pharmacy level, via wholesalers, by simply replenishing quantities of pharmaceutical products dispensed by the participating

pharmacies. Replenishment of the pharmaceutical trial product can be carried out and managed in accordance with the records of the database. Moreover, it is contemplated that participating pharmacies will be remunerated with a dispensing fee that can be determined based on the records of the database associated with the central computing station.

It is further contemplated that the present invention can be used with not just trial products, but also actual prescribed pharmaceuticals that are past the trial stage. The process and equipment are substantially the same. In a first embodiment, the product media acts as the prescription form and may include a field that indicates the pharmaceutical product to be prescribed, a quantity of pharmaceutical product complete with size of dosage if appropriate, and a number of validations available. The number of validations is representative of the number of refills that may be obtained. As the patient acquires the refills, the number of refills or validations field is decremented. Once the number of refills is exhausted, the patient is precluded from securing additional refills without a new prescription. Alternatively, a product media could be unique for each pharmaceutical. However, this approach requires a substantial inventory of product media at the prescriber's disposal.

Other objects and advantages of the present invention will become apparent and obvious from a study of the following description and the accompanying drawings, which are merely illustrative of such invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic illustration of the system of the present invention for managing the distribution of pharmaceutical trial products.

Figure 2A is a front side view of the pharmaceutical trial product media that forms a part of the present invention.

Figure 2B is a back side view of the pharmaceutical trial media.

Figure 3A is a front side view of the authorization media that forms a part of the present invention.

Figure 3B is a back side view of the authorization media.

Figures 4A-4B depicts a flow chart that shows the basic steps entailed in distributing, tracking and managing pharmaceutical trial product distributed in accordance with the present invention.

Figure 5 is a flow chart that depicts the basic steps entailed in terminal initialization, whether it be at the prescriber or pharmacy level.

Figures 6A-6D depicts a flow chart that shows the basic steps involved in the prescribers activating pharmaceutical trial media.

Figures 7A-7E depicts a flow chart that shows the basic steps involved in validating activated product trial media and dispensing pharmaceutical trial products in response to the validation of product trial media.

DETAILED DESCRIPTION OF THE INVENTION

With further reference to the drawings and particularly to Figure 1, the system utilized for carrying out the present invention is shown therein and indicated generally by the numeral 10. System 10 includes a central computing station 12 that has associated therewith a database for storing data and information communicated to the central computing station 12 during various steps or phases of the pharmaceutical trial product distribution process. As will be appreciated from subsequent portions of this disclosure, the present invention contemplates the utilization of participating medical doctors or prescribers and pharmacies to effectuate the distribution of pharmaceutical trial products. In order to communicate with the central computing station 12,

each participating prescriber and pharmacy is provided with a terminal communicatively linked with the central computing station 12. Therefore, it is appreciated that the system 10 of the present invention will include prescriber terminals 14 located at various participating prescriber sites and pharmacy terminals 16 located at various participating pharmacy sites. Both the prescriber terminals 14 and the pharmacy terminals 16 are capable of communicatively linking encoded media with the central computing station 12 where the encoded information associated with the media can be recorded in the associated database. Various types of communication terminals can be utilized at prescriber and pharmacy sites. However, as will be appreciated from subsequent portions of this disclosure, one such type of terminal is a conventional magnetic card reader that is adapted to accept magnetic cards and to read or interpret encoded information provided thereon and to communicate with the central computing station 12.

System 10 further includes what is referred to as a pharmaceutical product trial media that in Figure 1 is indicated by the numeral 18. As will be appreciated from subsequent portions of the disclosure, the product trial media 18 identifies and is associated with a particular pharmaceutical trial product and is transferred and passed between participating prescribers, patients and pharmacies. The product trial media 18 is particularly encoded with pertinent information that identifies a particular pharmaceutical trial product and is designed to be compatible with the prescriber and pharmacy terminals 14 and 16. In particular, prescriber and pharmacy terminals 14 and 16 are capable of reading the product trial media 18 and communicating encoded information associated therewith to the central computing station 12 for processing and recordation.

Although the type and quantity of encoded information on the product trial media 18 can vary, it is contemplated that each individual product trial media 18 would be encoded with at least the following information:

- a) media identification number;
- b) product identification number;
- c) product name;
- d) product form;
- e) product size;
- f) product quantity;
- g) media type;
- h) a series of manufacturer I.D. numbers;
- i) a date range.

In addition, as illustrated in Figures 2A and 2B, each individual product trial media 18 will have printed or embossed thereon certain identifying information such as:

- a) pharmaceutical manufacturer's name;
- b) product name (trade name, generic name);
- c) product form;
- d) product size;
- e) product quantity;
- f) media identification number;
- g) prescriber, patient and pharmacy signature areas;
- h) prescriber and pharmacy approval code areas.

The product trial media 18 can assume various tangible forms. However, in the example illustrated in Figures 2A and 2B and discussed herein, the product trial media 18 is in the form of a conventional magnetic card which again is designed to be compatible with a READ-ONLY magnetic reader terminal located at prescriber and pharmacy sites.

It should be appreciated that the product trial media 18 can be used with approved pharmaceuticals that are past the trial stage. Little if any change need be made to the above listed identifying information. However, it may be desirable to include a field that lists the number of refills or remaining validations, if any, that are available to the patient. This field may be

decremented each time the prescription is filled. Further, the product media may include fields which designate one of a plurality of participating pharmaceutical products, a quantity and dosage field as needed, or other comparable information that traditionally be located on a prescription sheet. While it is contemplated that one product media could be used for a plurality of pharmaceuticals, but it is also contemplated that each pharmaceutical could have its own product media. This may result in excess inventory for the prescriber, but is a viable embodiment of the present invention.

Finally, the system 10 of the present invention includes authorizing media indicated by the numeral 20 that is distributed to participating prescribers and pharmacies. As with the product trial media 18, the authorizing media 20 can be in various tangible forms and in the example illustrated herein, the authorizing media assumes a READ-ONLY magnetic card form that is compatible with the prescriber and pharmacy terminals 14 and 16. Each individual authorizing media specifically identifies a participating prescriber or pharmacy. In the case of prescriber authorizing media, the same would be encoded with various identifying information such as:

- a) the prescriber's name,
- b) prescriber's medical identification number,
- c) prescriber's control I.D. number,
- d) prescriber location identification.

In the case of pharmacy authorizing media, the same would include encoded information specific to and identifying a particular participating pharmacy. The encoded information on such a pharmacy authorizing media would include identifying information such as:

- a) pharmacy name,
- b) name of individual pharmacists associated with the identified pharmacy,
- c) pharmacy control identification number, and
- d) pharmacy location identifier.

Also, as illustrated in Figures 3A and Figures 3B, the authorization media 20 includes printed or embossed information thereon such as prescriber or pharmacy I.D. number, pharmacy or prescriber name, card expiration date, and space for the signature of a physician or pharmacist.

As will be discussed in more detail later, the authorizing media 20 is compatible with the prescriber and pharmacy terminals 14 and 16 and consequently, encoded identifying information associated with the individual authorizing media 20 can be reviewed and verified by the central computing station 12 prior to the participating prescribers and pharmacies having access to the central computing station. The authorizing media 20 enables the system and the central computing station 12 in particular to verify that prescribers and pharmacies attempting to enter the system and network are in fact authorized to do so and are in fact authorized participants in the pharmaceutical trial product distribution program of the present invention.

The present invention entails a pharmaceutical trial product distribution method or process where pharmaceutical trial products are actually prescribed by a participating medical doctor or prescriber and not directly delivered to the patient by the prescriber as is conventional practice today. Additionally, normal pharmaceuticals past the trial stage may similarly be so prescribed. Once the pharmaceutical product has been prescribed, the patient then proceeds to a participating pharmacy where the prescription for the trial, sample, or normal pharmaceutical product is filled. Prescriber and pharmacy transactions are all monitored and recorded by the central computing station 12. Periodically, the participating pharmacies are compensated for the trial product and normal products dispensed and the services performed. Compensation would typically include replenishment of dispensed trial or normal product through a wholesaler plus a dispensing fee, all of which is established by recorded transactions within the central database.

It is contemplated that the present system and method for distributing pharmaceutical products would be managed by an independent entity referred to as a program manager and that a number of pharmaceutical manufacturers would join together in a consortium or the like to participate in the pharmaceutical trial product distribution program, all of which would be administered and managed by the program manager. However, it is to be appreciated that the present pharmaceutical trial product distribution system and method can be carried out in other forms including a program administered and managed totally by a single pharmaceutical manufacturer. The same is true if the present invention is used for products past the trial stage.

In developing and implementing the pharmaceutical trial product distribution program or other pharmaceutical product program of the present invention, participating prescribers and pharmacies must be established. In this regard, it is contemplated that the program manager in cooperation with participating pharmaceutical manufacturers or suppliers, sometimes referred to as pharmaceutical members, identify certain prescribers and pharmacies that are authorized to participate in the program. Thereafter, the program manager issues specific authorizing media 20 to each of the prescribers and pharmacies authorized to participate in the program. Note that each authorizing media 20 is specifically encoded to identify a certain prescriber or pharmacy as well as the physical location or locations of that prescriber or pharmacy. In addition to the authorization media 20, prescriber terminals 14 and pharmacy terminals 16 are also delivered to the participating prescribers and pharmacies.

The prescriber and pharmacy terminals 14 and 16 are transaction-based communication units provided with both an EPROM chip and random access memory (RAM) for application operation. Each terminal is electrically powered and adapted to communicate with the central computing station or host 12 through a conventional telephone system. A user keypad having

both function keys and a ten-number keypad are incorporated into each terminal. Application, prompt, and approval instructions are communicated through an LED display that forms a part of each terminal.

The EPROM chip of each terminal is provided with a series of data fields that are used in a terminal initialization procedure that is designed to verify that a respective terminal is properly located physically and is under the control of an authorized and participating prescriber or pharmacy. In the way of example, the data fields of the EPROM chip could include: terminal serial number, prescriber or pharmacy identification, location or locations (physical address) for the participating prescriber or pharmacy assigned to that terminal, and location fax and telephone number. In addition, the EPROM chip of each terminal would include a check digit/analog code matrix used in establishing the authenticity of the terminal.

Now, turning to the RAM of the respective terminals, it is appreciated that the capacity of the RAM may vary but it is contemplated a storage capacity of 32K bytes would be sufficient to handle downloaded application programming from the central computing station 12. Data fields for the RAM may include a series of server (central computer station) phone numbers, a check digit/analog code index field, check digit/analog code multiplier-divisor, check digit/analog answerer, check digit/analog code formula, and system date and time.

The above discussion deals generally with the basic prescriber and pharmacy terminals 14 and 16 that are contemplated to be used in carrying out the pharmaceutical trial product distribution method and program of the present invention. Details of the construction and programming of the terminals are not dealt with herein because such is not per se material to the present invention and further, because such terminal designs are well appreciated by those skilled in the art and are in fact commercially available. While various types of terminals may be

employed by participating prescribers and pharmacies, it is contemplated that a terminal design of a conventional magnetic card reader would be efficient and cost effective for the present pharmaceutical product distribution program.

Initially, various pharmaceutical members distribute individual product trial media 18 to participating medical doctors or prescribers. This distribution can be carried out by sales representatives of the pharmaceutical members. At the same time, the program manager (administrator of the pharmaceutical trial product distribution program) may distribute both terminals and authorizing media 20 to both participating medical doctors and pharmacies. It is appreciated that prior to the initiation of the program and in fact on an ongoing basis, the database associated with the central computing station 12 is loaded with data corresponding to the distributed product trial media 18 and authorization media 20 as well as data that identifies each individual terminal to be delivered to participating prescribers and pharmacies. Such is important in carrying out the various integrity checks that will form a part of the pharmaceutical trial product distribution program of the present invention. The same is likewise true of prescriptions for products that are outside of the trial stage since these too are subject to strenuous regulatory reporting concerns.

Prior to entering the system and participating in the pharmaceutical distribution program, each participating prescriber and pharmacy must proceed through a terminal initialization process. This terminal initialization process, as illustrated in Figure 5, is designed to discover and identify unauthorized participants and to generally prevent unauthorized use of the system.

To initialize a terminal, the prescriber or pharmacy connects the terminal to an AC power outlet and a conventional phone line. Once the terminal is placed in an "on" state, the prescriber or pharmacy presses a "setup" function key. The terminal then automatically responds and

requests information pertinent to the data fields of the EPROM chip. In the way of examples, the terminal requests the user to input into the issued terminal the terminal serial number, practice name or pharmacy operating from the location of the terminal, the physical address of the location of the terminal, location communication telephone number, location business telephone number and location fax number.

Next, and still as a part of the terminal initialization process, the terminal requests that the prescriber or pharmacy user enter its issued authorization media 20. In the case of a magnetic card media and reader, the prescriber or pharmacy simply swipes its authorization media card 20 through a magnetic card reader and encoded data on the authorization media card 20 is recorded in the RAM of the terminal.

Thereafter, the terminal automatically dials and connects to a terminal initialization service that forms a part of the central computing station 12. The initialization service then uploads all data from the terminal into the database of the central computing station 12 including data recorded on the EPROM chip and information previously encoded on the authorization media 20 and now stored in the RAM of the terminal.

Based on independently entered reference data previously entered into the database of the central computing station, the data uploaded from the terminal during this initialization process can be checked against the reference data already stored in the database of the central computing station. At this point, the central computing station can verify whether a certain serial number terminal is properly coupled with a certain physical location and with a certain prescriber or pharmacy. If all relevant data uploaded from the terminal does not correspond to the reference data then the initialization process is failed and access to the system and program is denied.

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In the specific initialization method being discussed herein, the above does not complete the total initialization process. After passing the above, the individual prescriber or pharmacy is requested to enter a personal identification code, commonly referred to as a PIN. The personal identification code is furnished confidentially to the participating prescribers and pharmacies through the program manager and can be permanent or temporary. If temporary, the user will be subsequently requested to enter a personally devised code which becomes the user's permanent identification or PIN code. In any event, after the central computing station has requested entry of the user's personal identification code, the participating prescriber or pharmacy then enters the personal identification code into the system database and the central computing station then verifies the personal identification code and cross-checks the same with respect to uploaded terminal data, that is, data found on the EPROM chip and the terminal's RAM. If the personal identification code entered is determined to be an invalid personal identification code for any reason, the prescriber or pharmacy is denied access to the system. On the other hand, if the personal identification code is deemed to be valid then the central computing station indicates on the terminal's display "downloading application". At this time, the system's application is then downloaded into the terminal's RAM storage. Thereafter, the terminal displays "download complete" and this completes the terminal initialization process. The initialized terminal is then ready to be used on a periodic basis in the pharmaceutical trial distribution program of the present invention. Note that this same initialization process is carried out for both participating prescribers and pharmacies.

The product trial media 18 or other pharmaceutical product media delivered to the participating prescribers arrive in an unactivated state. That is, the product media in an unactivated state cannot be validated by a participating pharmacy and accordingly,

pharmaceutical product identified by that media cannot be dispensed. In essence, the pharmaceutical product media are blank prescription forms and have not been filled in by the prescriber or “validated” according to the present invention. In the method of distributing pharmaceutical product of the present invention, the participating prescribers actually activate the product media through a procedure where the product media is communicatively linked with the central computing station or host 12 via a prescriber’s terminal. See Figures 6A-6D which show a flow chart that depicts the basic steps involved in the activation process. However, before any unactivated product media can be activated by a prescriber, the prescriber must establish authorization. This can be carried out in a variety ways. In one embodiment of the present invention, activation of product media 18 is conditioned first upon the prescriber evidencing a valid authorization media. This is accomplished by the prescriber’s terminal reading the prescriber’s authorization media 20. Encoded information associated with the prescriber’s authorization media 20 is recorded within the RAM of the prescriber’s terminal. In particular, the terminal records the prescriber’s identification number associated with the prescriber’s authorization media 20. At that point, the terminal requests the prescriber to enter the prescriber’s personal identification code. Next, the terminal requests the prescriber to enter the quantity (number) of pharmaceutical media that the prescriber desires to activate. Thereafter, the prescriber enters into the keyboard of the prescriber terminal the numeric quantity of product media 18 to be activated by the system. The prescriber terminal then prompts the prescriber to communicatively link the product media to be activated with the prescriber’s terminal. In cases where the product trial media 18 assumes the form of magnetic cards for example, the prescriber simply swipes the product trial cards to be activated through a card reader-type terminal. One by

one, the prescriber swipes the product trial media to be authorized through the prescriber's terminal. This is also true of other product media.

As each product trial media is read by the prescriber's terminal, an authenticity check is made by the terminal. Specifically, the prescriber's terminal authenticates each product trial media read into the terminal. While various forms of authentication can be performed, in the present method, authenticity is established by the prescriber's terminal checking the product trial media I.D. and verifying that a valid answer results from the various check digit/analog code fields stored in the terminal. If the product trial media is deemed authentic, then the prescriber's unit then displays "product trial media valid". If the prescriber terminal determines that the product trial media is not valid, the terminal indicates such and the product trial media is not activated.

Once the prescriber has completed the activation of a certain number of product trial media the prescriber terminal dials a central computing station 12. At this point, the prescriber terminal uploads stored information corresponding to the prescriber authorization media and the prescriber identification code to the central computing station 12. The central computing station 12 validates the prescriber authorization media and the personal identification code. Once this validation has been established the central computing station uploads all of the product trial media information previously read into the prescriber's terminal during the present activation procedure. It is at this time that the central computing station 12 approves the "activation" of the entered product trial media and issues a specific approval code to the prescriber. The prescriber then records the prescriber approval code onto the face of the respective individual product trial media just activated. Once certain product trial media 18 has been activated, the central computing station 12 denotes in its associated database that certain product trial media 18 has

been activated, the activation date, and the identity of the prescriber activating the product trial media. The prescriber then appropriately stores the activated product trial media 18.

The same procedure is likewise applicable to more traditional prescriptions. In such a case, the prescriber receives a prescription media comparable to the product trial media 18 and activates it substantially identically to the technique described with reference to the product trial media 18. Additionally, the prescriber may indicate a number of refills to which the patient is entitled. Further, the prescriber may be required to enter the particular pharmaceutical that is being prescribed, quantity, and other comparable information. If each product media represents a different pharmaceutical, such may not be required.

To dispense the pharmaceutical trial product represented by the activated product trial media, or the prescription drug represented by the prescription media the prescriber signs the product trial media or alternative media and delivers the same to a participating patient. The patient in turn presents the activated media to a participating pharmacy for the purpose of filling the prescription of the prescriber.

Prior to actually filling the pharmaceutical prescription, the participating pharmacy, like the prescriber, must establish authorization. First, like the prescriber, the pharmacy terminal is subjected to the initialization test discussed above. This basically establishes that the issued terminal to the participating pharmacy is in fact the correct terminal, is properly physically located, and is associated with the assigned pharmacy. Again, this initialization procedure, as discussed above, is not contemplated to be a daily procedure but is only a basic initialization step for the participant utilizing the terminal and the system.

However, before the pharmacy can fill the prescription of any presented media 18, the media must be subjected to a “validation” procedure. The “validation” procedure is basically

illustrated in Figures 7A-7E. Essentially, this validation procedure establishes that the presented media 18 is authentic, still within an acceptable date range, has been activated by a prescriber, and has not previously been validated, or if previously validated, still has valid refills available. Once validation is established for any presented media, then the participating pharmacy can issue the prescriptive pharmaceutical product to the patient.

Details of the validation process will not be dealt with here in great detail because pharmaceutical “validation” of media parallels prescriber “activation” of the media just described. That is, “validation” by the participating pharmacy entails steps and procedures that are similar in function and result as the steps and procedures engaged in by the prescriber in activating certain media. But briefly, the validation step entails the participating pharmacy establishing authorization. This can be carried out in a variety of ways. However, in the process contemplated herein, the participating pharmacy would communicatively connect its authorization media 20 with the pharmacy terminal and after establishing a valid authorization media the participating pharmacy would enter its personal identification code. Thereafter, the terminal prompts the pharmacy to read the presented media 18 into the terminal. As an individual media is read into the pharmacist’s terminal, the terminal first checks for complete authenticity of the presented media 18. Like with the prescriber, the identification of the media is checked, the date range of the media is checked and the terminal seeks a valid answer from the check digit/analog code fields. If authenticity is not established, it follows that the participating pharmacy cannot dispense corresponding pharmaceutical product. However, if authenticity is established then the pharmacies’ terminal dials the central computing station and data and information from the pharmacies’ authorization media and personal identification is uploaded to the database of the central computing station 12. The central computing station establishes that

the uploaded information is valid and then information from the pharmacies' terminal related to the presented media 18 is uploaded to the central computing station. Assuming full validation, the central computing station issues a pharmacy approval code and the pharmacy records that approval code on the actual presented media 18. In addition, both the pharmacy and the patient sign the now validated media 18. Once validation is established the pharmacy then dispenses pharmaceutical product authorized by that valid media and permanently stores the validated media. At the same time, the central computing station 12 records the full validation data within its database by showing that a particular media 18 has been validated, the date of such validation, and the identity of the pharmacy validating the same.

Obviously, the database associated with the central computing station 12 will possess a full record of all transactions of the program including activations and validations. Importantly, the recorded transactions reveal the dispensing activities of each participating pharmacy. This serves as a basis for replenishing to the participating pharmacy pharmaceutical products dispensed in the present program and for the payment of dispensing these to the participating pharmacies. Typically, the pharmaceutical to be replenished can be replenished through wholesalers that serve the participating pharmacies.

A wealth of data can be discerned from the central computing database. For particular pharmaceutical members, data representing the identity of product and the quantity of a particular product prescribed and dispensed over a selected period of time is obviously readily available. More detailed data and records representing the specific activities of particular prescribers or pharmacies is also available. In the end, a wide variety of reports can be generated from the database. These reports can be so extensive and so detailed that the participating pharmaceutical members can study and evaluate "cause and effect" based on the recorded data.

In summary, the present method of tracking and managing the dispensing of pharmaceutical products centers around the utilization of a group of authorized prescribers and pharmacies and a centralized computing station that is specifically linked to the participating prescribers and pharmacies. Media capable of being exchanged at a pharmacy for pharmaceutical product are delivered in an unactivated state to participating prescribers. After establishing authorization, the prescriber through a remote terminal and the central computing station "activates" certain product media. Once activated, the product media is capable of being prescribed or exchanged for a pharmaceutical product at a participating pharmacy site. The activated pharmaceutical media 18 is then delivered to a patient and the patient in turn presents the same to a participating pharmacy. The pharmacy must establish authorization to participate in the system and thereafter the presented activated media is authenticated by the central computing station and is deemed valid. Next, the pharmacy dispenses the pharmaceutical product identified by that media. Thereafter, an audit and accounting function is performed based on the database associated with the central computing station. Accordingly, participating pharmacies can be compensated for the actual dispensed pharmaceutical product and for dispensing services performed.

The present method and program has been described as being carried out by utilizing magnetic cards and magnetic terminal readers. However, it is appreciated that other media forms and terminals could be utilized to carry out the basic method of tracking and managing the distribution of pharmaceutical trial products.

The present invention may, of course, be carried out in other specific ways than those herein set forth without parting from the spirit and essential characteristics of the invention. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive, and all

changes coming within the meaning and equivalency range of the appended Claims are intended to be embraced therein.

CLAIMS

What Is Claimed Is:

1. A method of dispensing, tracking and managing pharmaceutical products utilizing prescribers, pharmacies, and a central computing station, comprising the steps of:
 - a) forming a series of product cards by encoding on respective product cards information that identifies a particular pharmaceutical product;
 - b) issuing the product cards to participating prescribers;
 - c) activating the product cards after issuance to prescribers by the prescribers communicatively linking the product cards to the central computing station and wherein activation is established by the central computing station verifying the authenticity of the product cards, recording selected information encoded on the product cards in a database associated with the central computing station, and finally approving activation;
 - d) transferring a respective activated product card from a prescriber to a patient;
 - e) the patient in turn presenting the activated product card to a participating pharmacy;
 - f) validating the activated product card at the pharmacy by the pharmacy communicatively linking the presented product card with the central computing station and verifying that the presented product card has in fact been activated and not previously validated;
 - g) after validating the presented product card, the pharmacy then dispensing the approved pharmaceutical product to the patient; and

- h) periodically accounting to the participating pharmacies for pharmaceutical product dispensed in accordance with the records of the database associated with the central computing system.

2. The method of claim 1 wherein the product cards when delivered to a prescriber are in an unactivated state and wherein the activation of the product cards takes place while the same are in the possession of a prescriber.

3. The method of claim 2 further including the step of issuing an authorization card to the participating prescribers and wherein activation of the product card is conditioned upon respective prescribers establishing authorization.

4. The method of claim 3 including the step of establishing prescriber authorization by communicatively linking a prescriber's authorization card with the central computing station and verifying the authenticity of the prescriber's authorization card.

5. A method of dispensing, tracking and managing pharmaceutical products utilizing prescribers, pharmacies, and a system including a central computing station and database, comprising the steps of:

- a) forming a product media and encoding that media with information that identifies a particular pharmaceutical product;
- b) issuing the product media to one or more prescribers;
- c) activating the product media by a prescriber communicatively linking the product media to the central computing station wherein the central computing station records encoded information from the product media into a database associated with the central computing station and thereby activates the product media;

- d) the step of activating the product media including entering data associated with the product media into a terminal and thereafter uploading data associated with the product media from the terminal to the central computing station;
- e) transferring the activated product media from a prescriber to a patient;
- f) the patient then presenting the activated product media to a pharmacy;
- g) validating the product media at the pharmacy by communicatively linking the presented product media with the central computing station which determines if the presented product media has in fact been activated by a prescriber and if activated, the central computing station approves dispensing of the pharmaceutical product identified and authorized by that product media;
- h) the step of validating the product media including entering data from the activated product media into a terminal and uploading that data from the terminal to the central computing station;
- i) after validating the presented product media, dispensing the approved pharmaceutical product to the patient; and
- j) periodically accounting to the participating pharmacies for pharmaceutical product dispensed in accordance with the records of the database associated with the central computing station.

6. The method of claim 5 wherein activation of the product media is conditioned upon the activating prescriber being an authorized prescriber, and wherein validation and

dispensing of the pharmaceutical product is conditioned upon the validating and dispensing pharmacy being an authorized pharmacy.

7. The method of claim 6 wherein authorization for both prescribers and pharmacies is established in part at least by issuing a uniquely identifying authorizing media to each participating prescriber and pharmacy and wherein the step of authorization entails prescribers and pharmacies establishing a communication link between the issued authorizing media and the central computing station wherein the central computing station effectively scans the issued authorizing media so as to authenticate the same.

8. The method of claim 7 wherein participating prescribers and pharmacies are provided with a communication terminal for communicating with the central computing station, and wherein prescriber and pharmacy authorization is further conditioned upon the initialization of the communication terminal associated with respective prescribers and pharmacies.

9. A system for tracking and managing the dispensing of pharmaceutical products utilizing medical prescribers and pharmacies, comprising:

- a) a central computing station having an associated database;
- b) a first array of communication terminals located remotely from the central computing station at various medical prescriber sites with each communication terminal communicatively linked to the central computing station;
- c) a second array of communication terminals located remotely from the central computing station at various pharmacy sites with each communication terminal communicatively linked to the central computing station;

- d) a pharmaceutical product media encoded with information identifying a particular pharmaceutical product;
 - e) the pharmaceutical product media assuming the form of individual media slips with each individual media slip including the encoding information particularly identifying the pharmaceutical product; and
 - f) wherein the prescriber terminals and the pharmacy terminals are capable of receiving and reading the encoded information associated with the individual pharmaceutical product media slips and communicating that information to the central computing station where the central computing station tracks and manages the movement of the individual pharmaceutical media slips between prescribers, patients and pharmacies and also controls the actual dispensing of the pharmaceutical product identified by the individual pharmaceutical product media slips.
10. The system for tracking and managing the distribution of pharmaceutical products of claim 9 further including a series of system authorization media slips with each authorization media slip including specific information particularly identifying an authorized medical prescriber or pharmacy and wherein the authorization media slips are transferred to the appropriate participating medical prescribers and pharmacies; and wherein the prescriber and pharmacy terminals are capable of reading the authorization media slips and communicating the encoded information thereon to the central computing station for authorization verification such that after authorization has been established, authorized prescribers or pharmacies are

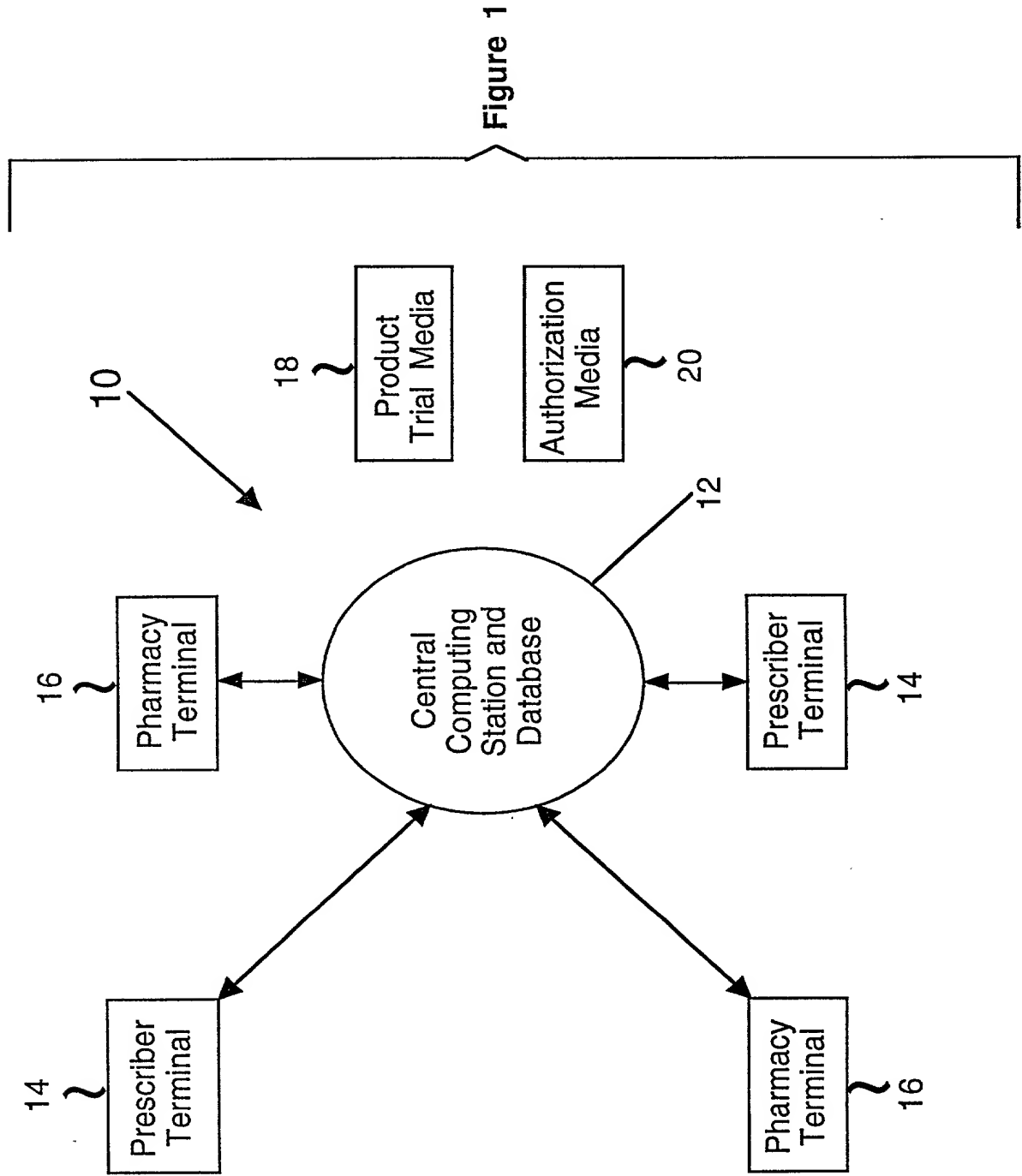
then permitted access to the system for purposes of prescribing or dispensing pharmaceutical products.

11. A method of prescribing and dispensing prescription pharmaceutical products comprising:
 - a. forming a pharmaceutical product media and encoding that media with information that identifies one or more particular prescription pharmaceutical products;
 - b. issuing the pharmaceutical product media to one or more prescribers;
 - c. activating the pharmaceutical product media and transferring the activated pharmaceutical product media from a prescriber to a patient, wherein the activated pharmaceutical product media identifies one or more prescription pharmaceutical products that have been prescribed by the prescriber for the patient; and
 - d. presenting the activated pharmaceutical product media to a pharmacy that fills the prescription identified by the pharmaceutical product media.
12. The method of claim 11, wherein activating the pharmaceutical product media entails a prescriber communicatively linking the pharmaceutical product media to a central computing station where the central computing station records encoded information from the pharmaceutical product media into a database associated with the central computing station.
13. The method of claim 11, wherein the pharmacy validates the pharmaceutical product media prior to fulfilling the prescription identified thereby.

14. The method of claim 12, wherein the validation of the pharmaceutical product media by the pharmacy includes communicatively linking the presented pharmaceutical product media with a central computing station which determines if the presented pharmaceutical product media has in fact been appropriately issued by a prescriber.
15. The method of claim 13, wherein prescribers activate the pharmaceutical product media prior to the same being issued to a patient, and wherein the activation by the prescriber includes the prescriber communicatively linking the pharmaceutical product media to a central computing station wherein the central computing station records encoded information from the pharmaceutical product media into a database associated with the central computing station, and wherein validation by the pharmacy includes communicatively linking the presented pharmaceutical product media with the central computing station to determine if the pharmaceutical product media has in fact been activated by a prescriber.
16. The method of claim 11, wherein the pharmaceutical product media includes a plurality of data fields, including at least one data field for identifying at least one prescribed pharmaceutical product, and associated data fields for identifying the quantity and number of refills for the associated prescribed pharmaceutical product.

ABSTRACT OF THE INVENTION

A new and improved method of dispensing, tracking and managing pharmaceutical product samples by communicatively linking prescribers and pharmacies to a central computing station. The present invention entails utilizing product trial media that is exchanged for actual pharmaceutical product. The media is encoded with information that identifies a particular pharmaceutical trial product, such as by magnetic encoding similar to that used with credit cards. The media is distributed to participating medical doctors or prescribers who then activate the media via the central computing station. The prescriber then transfers the activated media to patients who then present the media to participating pharmacies. Before filling the pharmaceutical trial product identified by the media, the pharmacy validates the media via a link with the central computing station. Then, the pharmacy dispenses the prescribed pharmaceutical trial product. The central computing station also includes a database that records data related to the use of the media so that all pharmaceutical trial products can be accounted for.



18



TRIAL PRODUCT TRADE NAME
TRIAL PRODUCT GENERIC NAME
TRIAL PRODUCT FORM & STRENGTH
TRIAL PRODUCT QUANTITY

CARD SERIAL NUMBER
CARD EXPIRATION DATE

Figure 2A

18



Physician
Approval Code
☐☐☐☐

Pharmacist
Approval Code
☐☐☐☐

Physician Signature
Pharmacist Signature
Patient Signature

Figure 2B

Figure 3A



20

AUTHORIZER ID NUMBER

AUTHORIZER NAME
CARD EXPIRATION DATE

Figure 3B



20

continued	
1.00	1.00
0.99	0.99
0.98	0.98
0.97	0.97
0.96	0.96
0.95	0.95
0.94	0.94
0.93	0.93
0.92	0.92
0.91	0.91
0.90	0.90
0.89	0.89
0.88	0.88
0.87	0.87
0.86	0.86
0.85	0.85
0.84	0.84
0.83	0.83
0.82	0.82
0.81	0.81
0.80	0.80
0.79	0.79
0.78	0.78
0.77	0.77
0.76	0.76
0.75	0.75
0.74	0.74
0.73	0.73
0.72	0.72
0.71	0.71
0.70	0.70
0.69	0.69
0.68	0.68
0.67	0.67
0.66	0.66
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0.53	0.53
0.52	0.52
0.51	0.51
0.50	0.50
0.49	0.49
0.48	0.48
0.47	0.47
0.46	0.46
0.45	0.45
0.44	0.44
0.43	0.43
0.42	0.42
0.41	0.41
0.40	0.40
0.39	0.39
0.38	0.38
0.37	0.37
0.36	0.36
0.35	0.35
0.34	0.34
0.33	0.33
0.32	0.32
0.31	0.31
0.30	0.30
0.29	0.29
0.28	0.28
0.27	0.27
0.26	0.26
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0.23	0.23
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0.21	0.21
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0.19	0.19
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0.14	0.14
0.13	0.13
0.12	0.12
0.11	0.11
0.10	0.10
0.09	0.09
0.08	0.08
0.07	0.07
0.06	0.06
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0.04	0.04
0.03	0.03
0.02	0.02
0.01	0.01
0.00	0.00

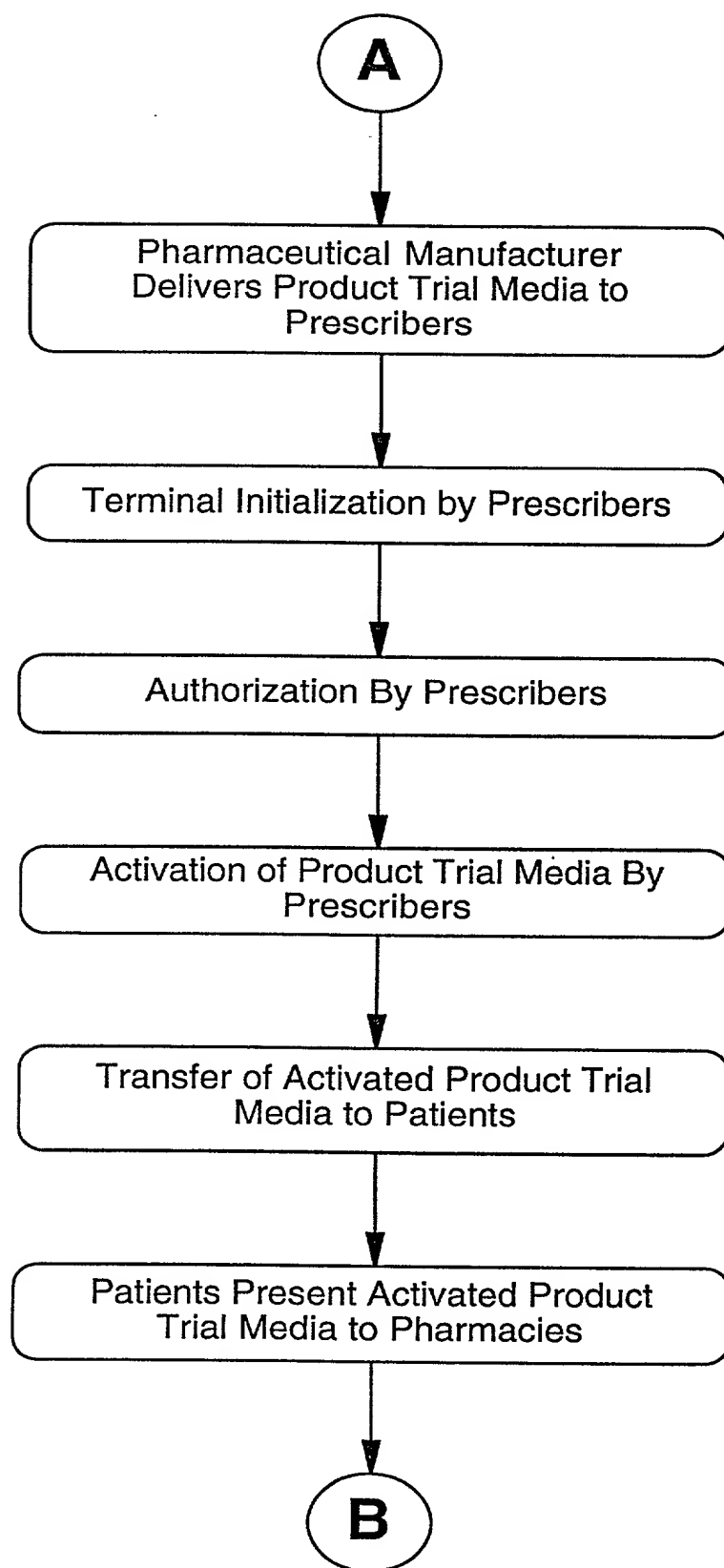


Figure 4A

B

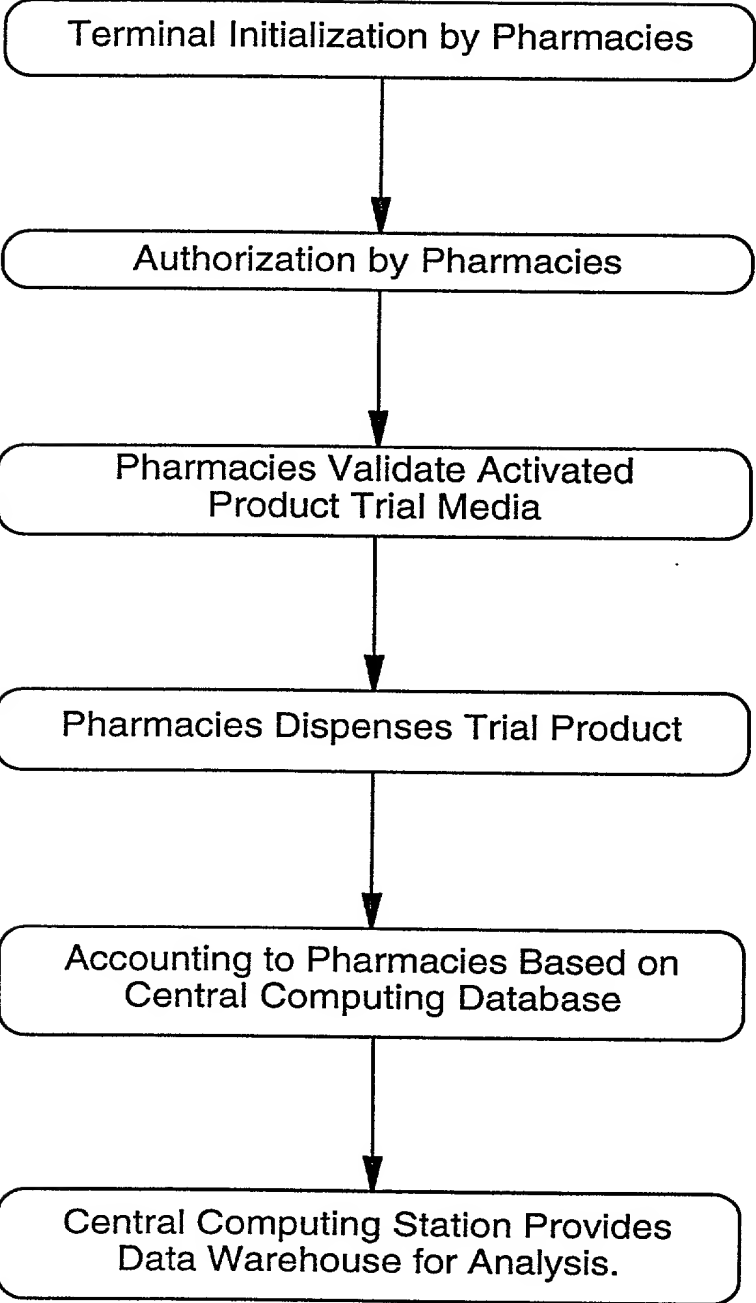


Figure 4B

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graph TD
    A[Entry Of Verifying Information Into Terminal  
a.) General data such as terminal serial number,  
name and address of terminal user  
b.) Authorization media] --> B[Uploading of Verifying Information From Terminal  
To Central Computing Station]
    B --> C[Central Computing Station Checks Entered  
Verifying Information Against Reference Data  
Previously Stored in The Central Computing  
Station]
    C --> D{Identifying  
Information  
Verified}
    D -- No --> E[STOP  
Initialization  
Process]
    D -- Yes --> F[User Enters Personal Identification Codes]
    F --> G{Personal  
Identification  
Codes  
Verified}
    G -- No --> H[STOP  
Initialization  
Process]
    G -- Yes --> I[Central Computing Station Downloads  
System's Application Into Terminal]
  
```

Figure 5

005240"092550

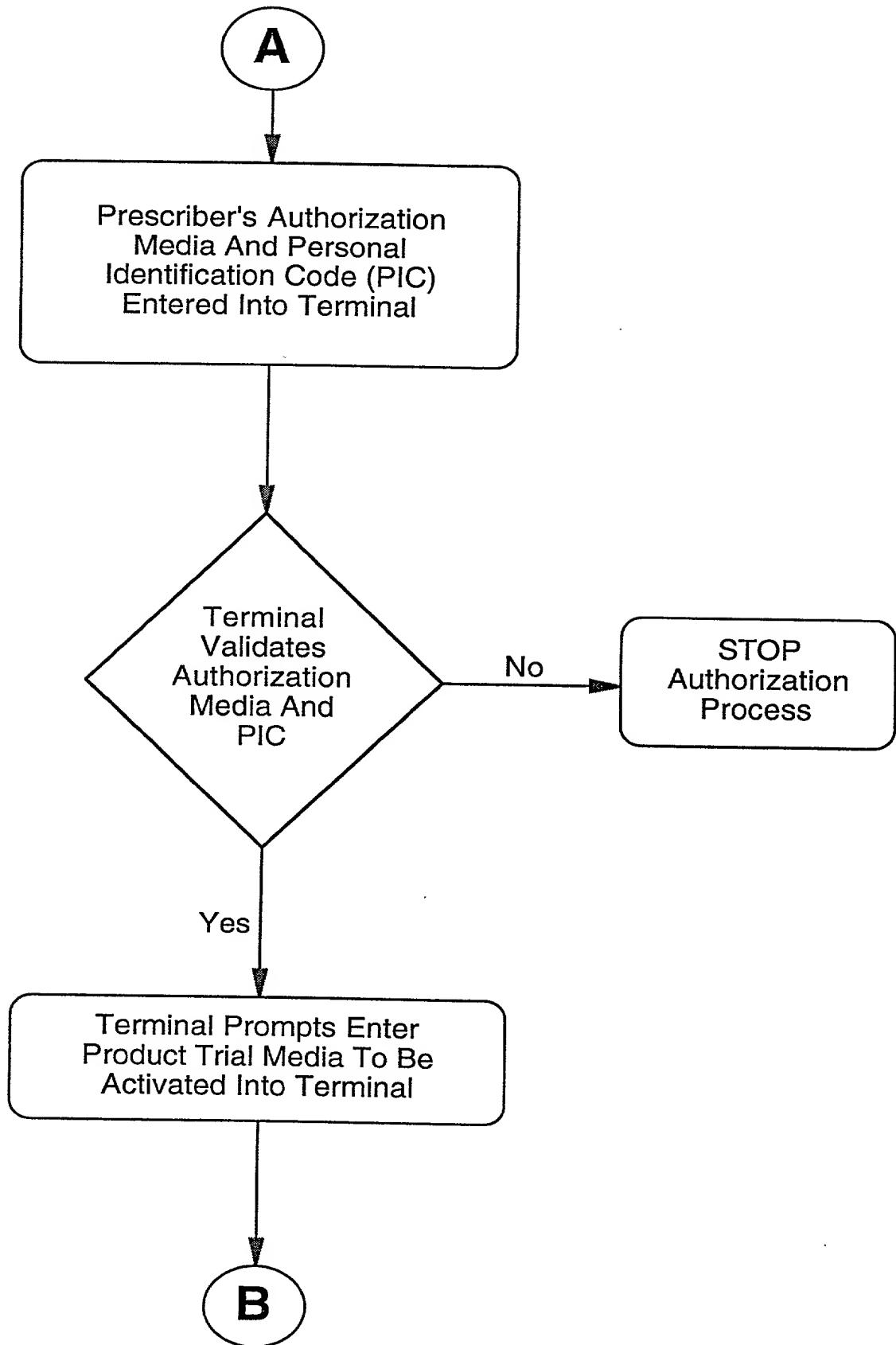


Figure 6A

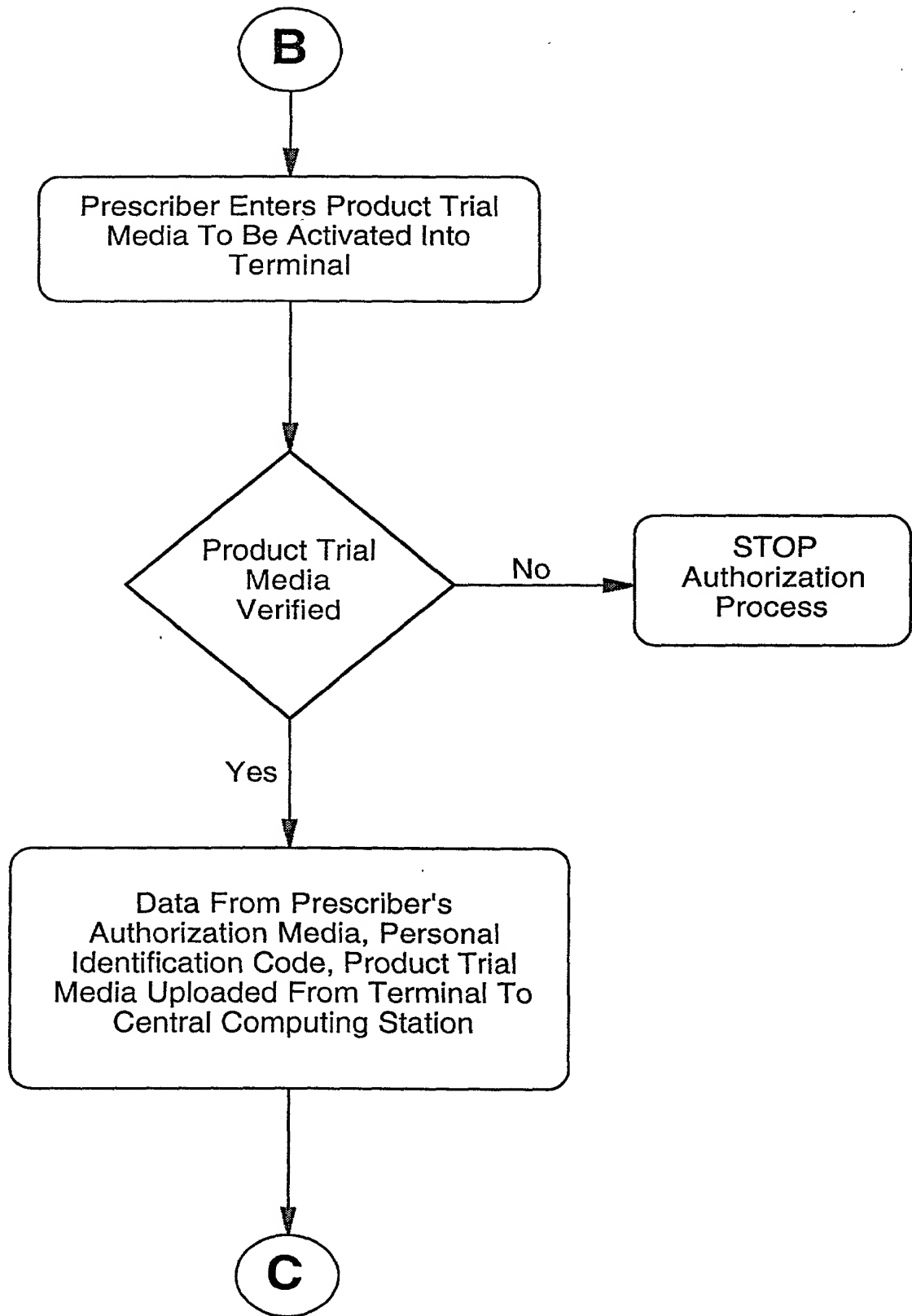


Figure 6B

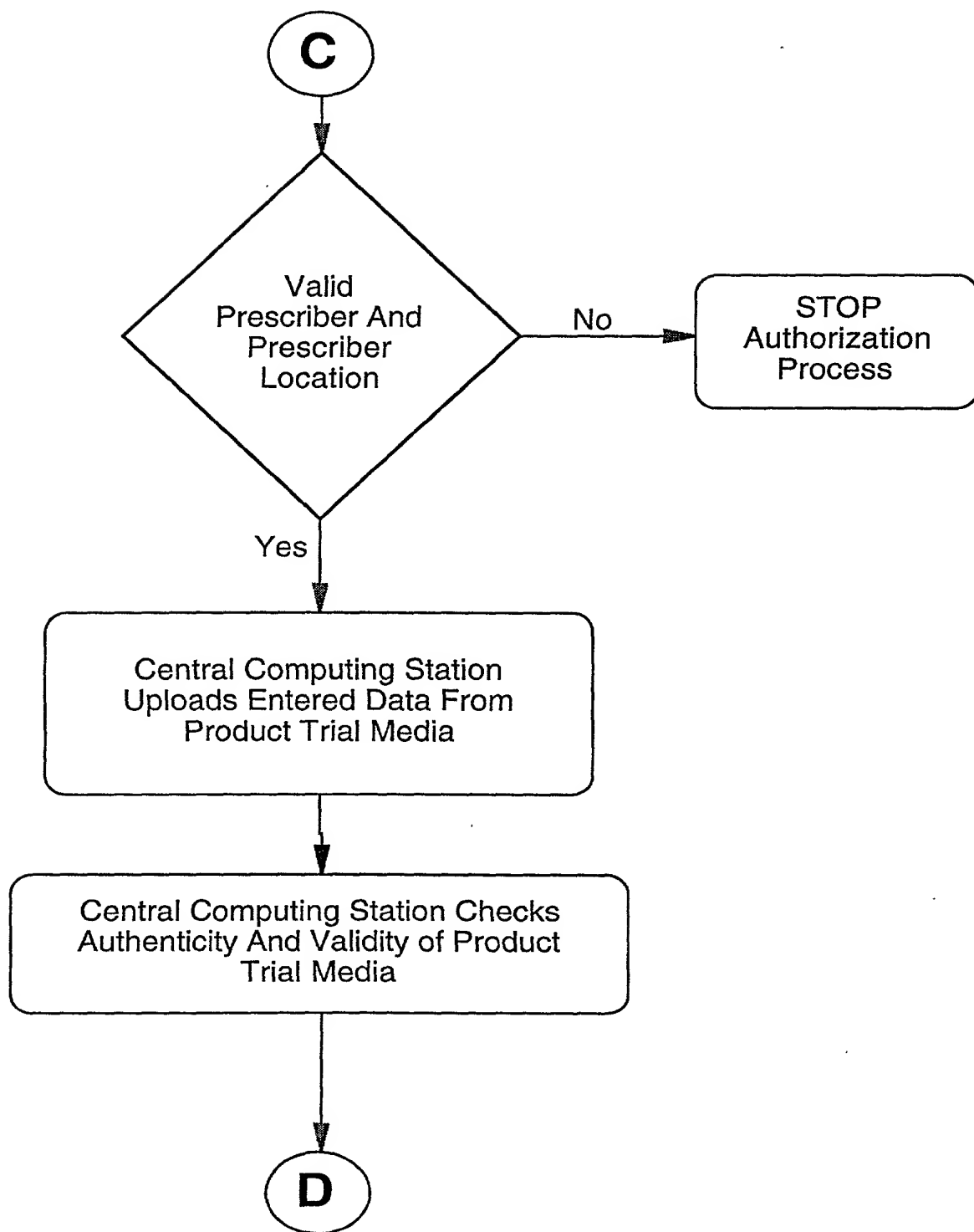


Figure 6C

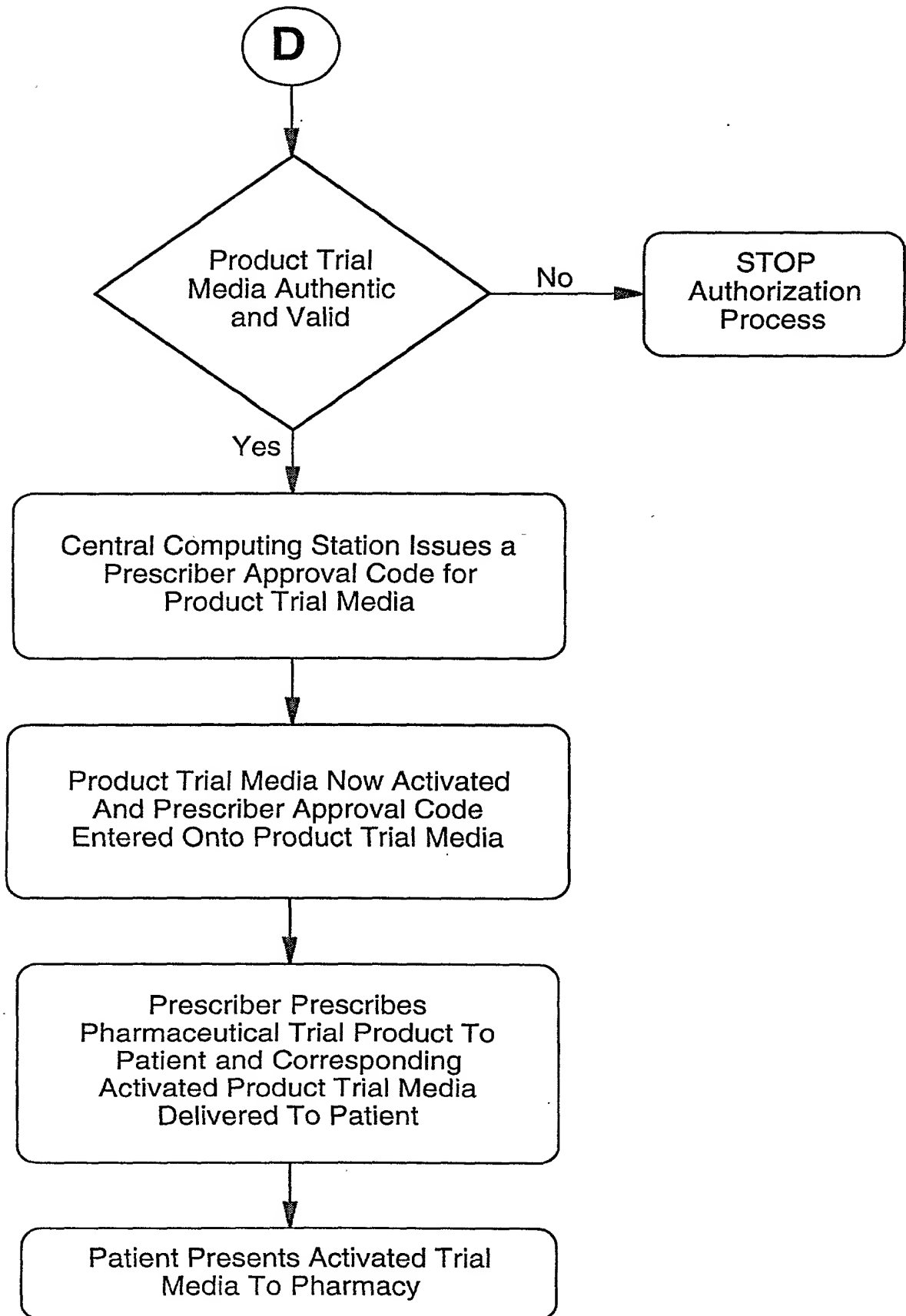


Figure 6D

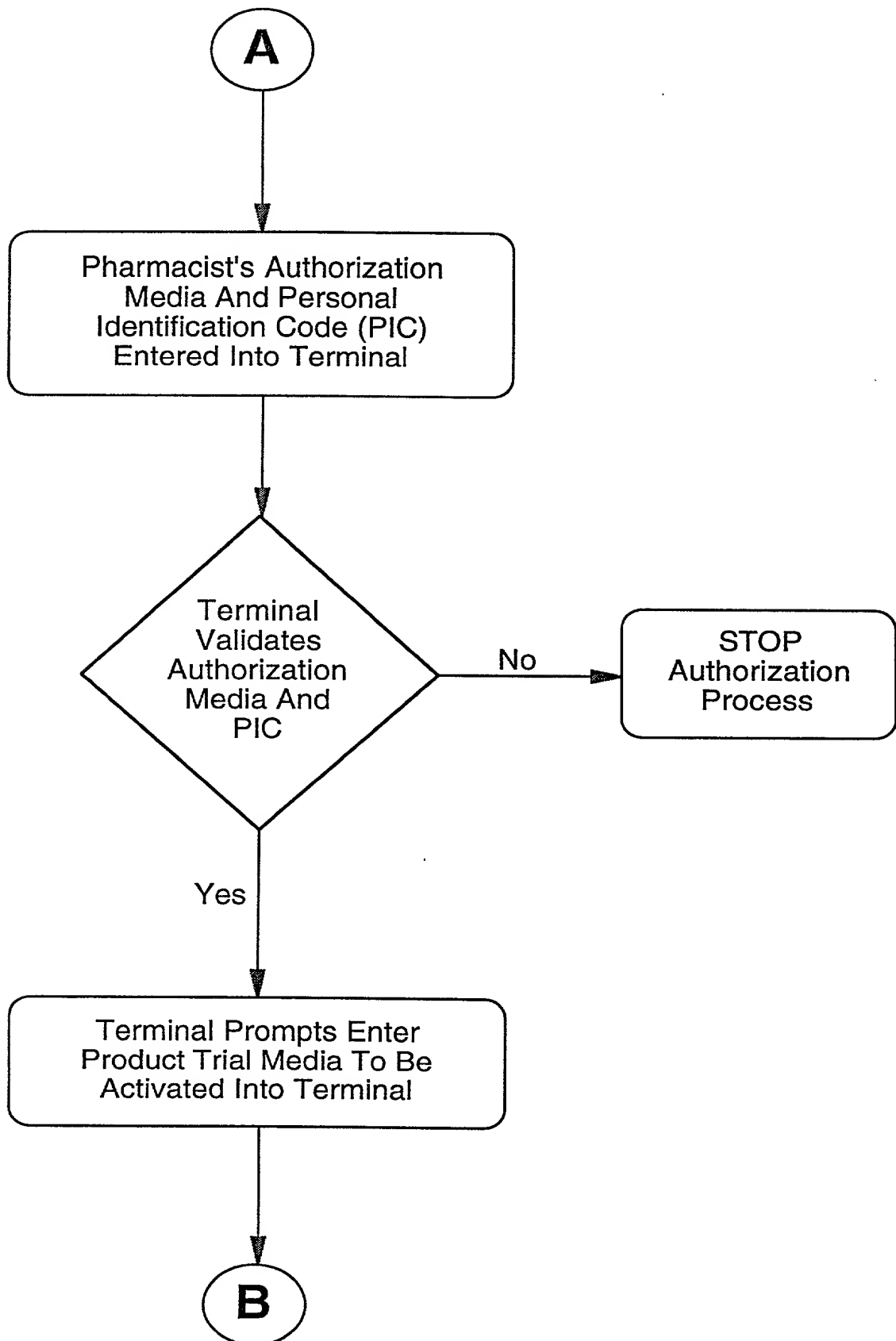


Figure 7A

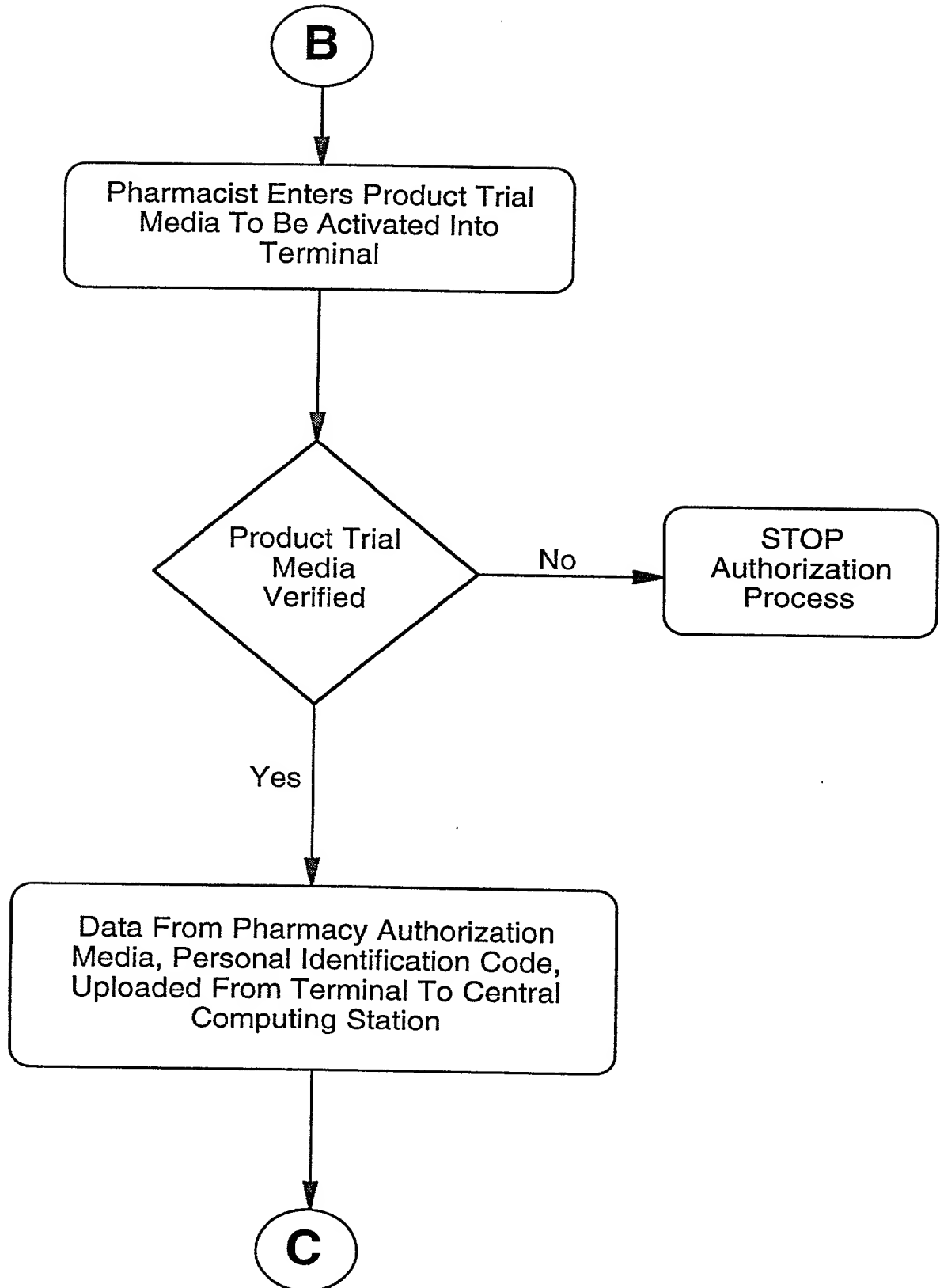


Figure 7B

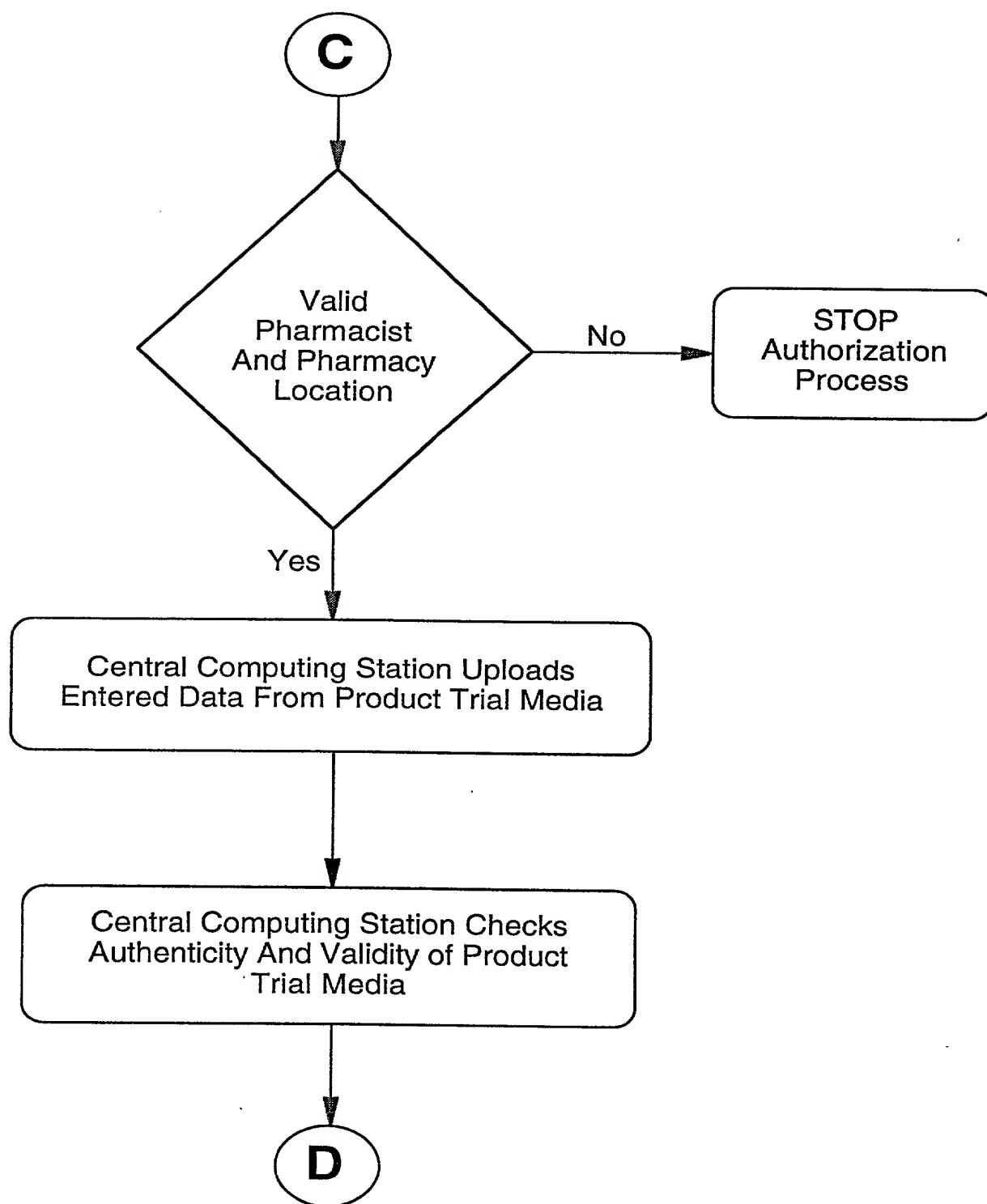
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Figure 7C

a) Age

Age Group	No (%)	Yes (%)
18-24	15	5
25-34	25	10
35-44	30	15
45-54	20	25
55-64	10	35
65+	5	15

b) Sex

Sex	No (%)	Yes (%)
Male	45	55
Female	55	45

c) Education

Education Level	No (%)	Yes (%)
Primary	10	5
Secondary	30	15
University	60	80

d) Income

Income Level	No (%)	Yes (%)
Low	40	25
Medium	35	35
High	25	40

e) Employment

Employment Status	No (%)	Yes (%)
Unemployed	35	15
Employed	65	85

f) Religion

Religion	No (%)	Yes (%)
Other	5	5
Christian	45	40
Muslim	50	55

g) Political affiliation

Party	No (%)	Yes (%)
Other	5	5
AKP	45	40
CHP	50	55

h) Attitude towards gay men

Attitude	No (%)	Yes (%)
Very liberal	5	15
Liberal	25	35
Conservative	70	50

i) Attitude towards lesbian women

Attitude	No (%)	Yes (%)
Very liberal	5	15
Liberal	25	35
Conservative	70	50

j) Attitude towards transgender people

Attitude	No (%)	Yes (%)
Very liberal	5	15
Liberal	25	35
Conservative	70	50

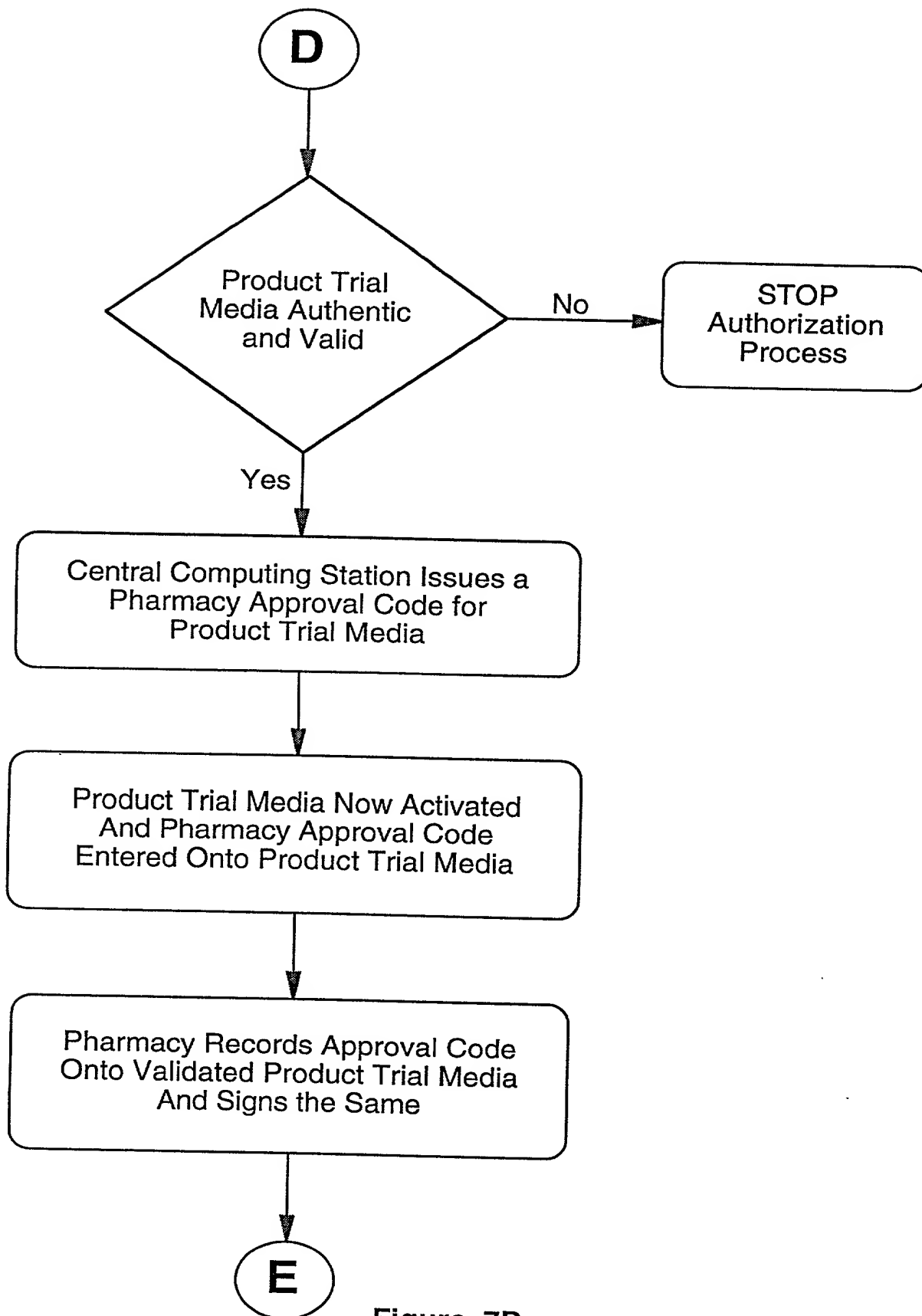


Figure 7D

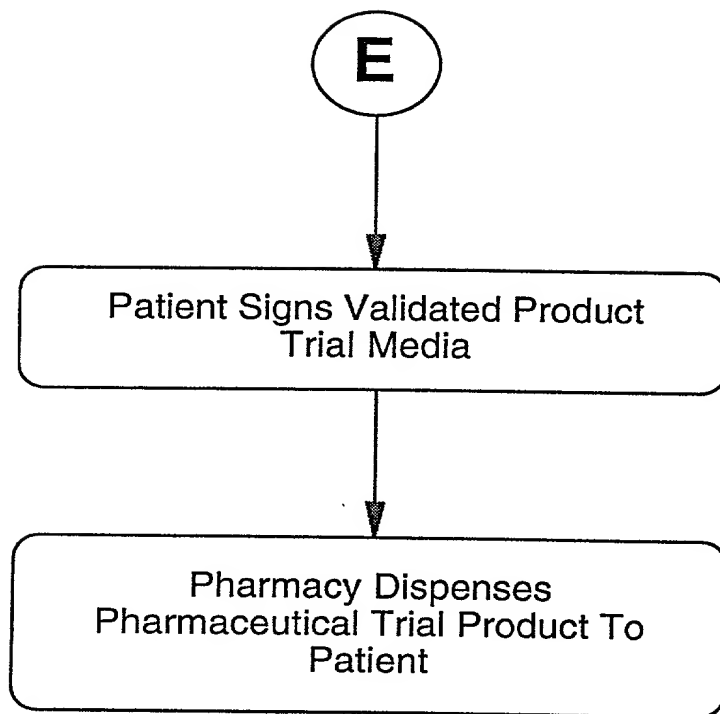


Figure 7E

RULE 63 (37 C.F.R. 1.63)
DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

As a below named inventor, I hereby declare that my residence, post office address and citizenship are as stated below next to my name, and I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: **METHOD AND SYSTEM FOR DISPENSING, TRACKING AND MANAGING PHARMACEUTICAL PRODUCTS**, the specification of which (check applicable box(es):

☒ (X) is attached hereto;

☐ was filed on _____ as U.S. Application Serial No. _____

☐ was filed as PCT international application No. PCT/_____/_____/_____ on _____ and (if applicable to U.S. or PCT application) was amended on _____.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with 37 C.F.R. 1.56(e). I hereby claim foreign priority benefits under 35 U.S.C. 119/365 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed or, if no priority is claimed before the filing date of this application:

Prior Foreign Application(s):

Application Number

Country

Day/Month/Year Filed

I hereby claim the benefit under 35 U.S.C. 120/365 of all prior United States and PCT International applications listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in such prior application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose material information as defined in 37 C.F.R. 1.56(e) which occurred between the filing date of the prior applications and the national or PCT international filing date of this application:

Prior U.S./PCT Application(s):

Application Serial No.

Day/Month/Year Filed

Status: patented, pending, abandoned

09/137,096

August 20, 1998

Patented, now U.S. Patent No. 6,055,507

08/556,466

November 13, 1995

Patented, now U.S. Patent No. 5,832,449

I hereby declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon. And I hereby appoint the firm of Coats & Bennett, P.L.L.C., comprising Larry L. Coats, Reg. No. 25,620; David E. Bennett, Reg. No. 32,194; John R. Owen, Reg. No. 42,066; David D. Kalish, Reg. No. 42,706; Taylor M. Davenport, Reg. No. 42,406; Steven N. Terranova, Reg. No. 43,185; and Edward H. Green, III, Reg. No. 42,604; of P.O. Box 5, Raleigh, NC 27602, (919) 854-1844 (all communications should be directed to Larry L. Coats); as my attorneys and/or agents with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

1) Inventor's Signature  Date 4/25/00

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First Middle Initial Family Name Citizenship

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